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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/679,638 | 10/06/2003 | Henrik Bengtsson | 6513.200-US | 3945 |

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| EXAMINER | |
|---|---|
| ALEXANDER, JOHN D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/679,638 | BENGTSSON, HENRIK | |
| | Examiner | Art Unit | |
| | John D. Alexander | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *October 6, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-13* is/are rejected.

7)☒ Claim(s) *6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/19/04, 5/5/04,*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following minor informality: it is suggested that the cross reference to related U.S. provisional application no. 60/419,222 be modified to include notice that the application is abandoned.

### *Claim Objections*

Claims 6 and 7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Here, Claim 6 is a multiple dependent claim that optionally depends from multiple dependent Claim 3. Furthermore, regarding Claim 7, there is no antecedent basis for the "infusion needle" of line 1 in its parent Claim 5. Instead, it appears that Claim 7 should have depended from Claim 6. Accordingly, the claims have not been further treated on the merits.

Claim 11 is objected to because of the following informality: the phrase "control means being adapted for identifying a predetermined condition or a signal and *apply* a" on line 8 of the claim is grammatically awkward. It is suggested that the phrase be changed to --control means being adapted for identifying a predetermined condition or a signal and *applying* a--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 3/1, 4, 5, and 8-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al (Patent No. 6175752). Say et al disclose an analyte monitoring device that includes all the limitations recited in these claims.

- Regarding **Claim 1**, Say et al disclose a fluid delivery device (Fig. 25, element 250) comprising: a reservoir adapted to contain a fluid and comprising, in a situation of use, associated outlet means, expelling means for expelling a fluid out of the reservoir through the outlet means (Fig. 25, element 260; Col. 54, lines 53-58), a voltage source (Fig. 18B, element 95), a pair of electrodes adapted to be mounted in conductive contact with the skin of a subject (Fig. 18B, elements 42 & 42'; Col. 7, lines 14-18 & 23-25; Col. 37, lines 64-67), control means adapted for identifying a predefined condition and applying a voltage between the pair of electrodes in response thereto, the flow of current between the pair of electrodes, in a situation of use, resulting in muscle stimulation (Fig. 1, element 44; Fig. 18B, elements 104 & 109; Fig. 25, elements 254, 258, & 262; Col. 7, lines 5-12; Col. 39, lines 61-62; Col. 40, line 13; Col. 45, lines 8-67; Col. 46, lines 12-15). Regarding the claimed "pair of electrodes," Say et al's disclosed electrical stimulation warning (Col. 7, lines 5-12) inherently comprises a pair of electrodes because the current flow of the stimulation shock must have a return path for a closed circuit. Additionally, regarding "expelling means...for..." on line 4 and "control means...for..." on line 9, examiner considers that applicant has invoked 35 U.S.C. 112 6$^{th}$ paragraph and that Say et al disclose the claimed functions and equivalent means.

- Regarding **Claim 3/1**, Say et al further disclose the fluid delivery device as defined in Claim 1, wherein the control means is adapted to receive remotely generated commands and to control the fluid delivery device in accordance therewith, the predefined condition belonging to the group of conditions comprising: receiving a command from a predefined groups of commands, receiving a predefined command, and performing a predefined control action in response to a received command (Fig. 18B, element 99; Col. 37, lines 31-32; Col. 43, lines 30-34).
- Regarding **Claims 4 and 5**, Say et al further disclose a mounting surface adapted for application to the skin of a subject, the pair of electrodes being arranged on the mounting surface, wherein the mounting surface comprises adhesive means which allows the device to be affixed to the skin of the subject user (Fig. 17; Col. 31, lines 63-67; Col. 32, lines 1-16).
- Regarding **Claim 8**, Say et al disclose a sensor device (Col. 2, lines 13-16) comprising: a sensor means adapted to be inserted transcutaneously through the skin of a subject and capable of being influenced by a body substance and producing a signal corresponding thereto (Fig. 1, element 42; Col. 3, lines 6-16; Col. 5, lines 28-32), control means adapted to receive signals from the sensor means and generate command signals in response thereto (Fig. 1, element 44; Col. 6, lines 55-67; Col. 7, lines 1-12), a voltage source (Fig. 18B, element 95), a pair of electrodes adapted to be mounted in conductive contact with the skin of a subject (Fig. 18B, elements 42 & 42'; Col. 7, lines 14-18 & 23-25; Col. 37, lines 64-67), wherein the control means is adapted for identifying a predefined condition on the basis of the command signals and applying a voltage between the pair of electrodes in response thereto, the flow of current between the pair of electrodes, in a situation of use, resulting in

muscle stimulation (Fig. 1, element 44; Fig. 18B, elements 104 & 109; Col. 7, lines 5-12; Col. 45, lines 8-67; Col. 46, lines 12-15). Regarding the claimed "pair of electrodes," remarks related above in rejection of Claim 1 apply here as well. Additionally, regarding "control means...for..." on line 10, examiner considers that applicant has invoked 35 U.S.C. 112 6th paragraph and that Say et al disclose the claimed functions and equivalent means. However, regarding "sensor means" on line 2 and "control means" on line 5, examiner considers that applicant has not invoked 35 U.S.C. 112 6th paragraph.

- Regarding **Claim 9**, Say et al further disclose that the command signals are in the form of a value indicative of a blood glucose level of the subject, and wherein the predefined condition belongs to the group of conditions comprising: a blood glucose level which is outside a given range, a signal from the sensor means is outside a given range, a low voltage condition for the voltage source, and a preset timer interval (Col. 5, lines 31-32; Col. 7, lines 9-12; Col. 45, lines 8-67).
- Regarding **Claim 10**, Say et al further disclose a mounting surface adapted for application to the skin of a subject, the pair of electrodes being arranged on the mounting surface, the mounting surface preferably comprising a pressure-sensitive adhesive which allows the device to be affixed to the skin of the subject user (Fig. 17; Col. 31, lines 63-67; Col. 32, lines 1-16).
- Regarding **Claim 11**, Say et al further disclose a signal device comprising: a first electrode adapted to be mounted in conductive contact with the skin of a subject, a second electrode adapted to be mounted in conductive contact with the skin of a subject, the first and second electrodes providing a pair of electrodes (Fig. 18B, elements 42 & 42'; Col. 7, lines 14-18 &

23-25; Col. 37, lines 64-67), a voltage source for providing a voltage between the pair of electrodes (Fig. 18B, element 95), control means for controlling the voltage applied between the pair of electrodes, the control means being adapted for identifying a predefined condition or a signal and applying a voltage between the pair of electrodes in response thereto (Fig. 1, element 44; Fig. 18B, elements 104 & 109; Col. 7, lines 5-12; Col. 45, lines 8-67; Col. 46, lines 12-15). Regarding the claimed "pair of electrodes," remarks related above in rejection of Claim 1 apply here as well. Additionally, regarding "control means for..." on line 7, examiner considers that applicant has invoked 35 U.S.C. 112 6th paragraph and that Say et al disclose the claimed functions and equivalent means.

- Regarding **Claim 12**, Say et al further disclose a mounting surface adapted for application to the skin of a subject, the pair of electrodes being arranged on the mounting surface, the mounting surface preferably comprising adhesive means which allows the device to be affixed to the skin of the subject user (Fig. 17; Col. 31, lines 63-67; Col. 32, lines 1-16).
- Regarding **Claim 13**, Say et al further disclose that the control means is adapted to receive remotely generated commands and to apply a voltage between the pair of electrodes in response thereto (Fig. 18B, element 99; Col. 37, lines 31-32; Col. 43, lines 30-34).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 2 and 3/2** are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al in view of Fischell (Patent No. 4619653).

- Regarding **Claim 2**, Say et al disclose a fluid delivery device as related above in rejection of Claim 1, and further disclose a watchdog circuit that tests operating conditions of the device circuitry and may activate a stimulation warning if an error is detected (Fig. 18B, element 103; Col. 47, lines 33-47). Say et al do not explicitly disclose that the watchdog circuit tests for a predefined condition belonging to the group of conditions comprising: an actual fluid delivery rate which differs from a preset fluid delivery rate, a pressure in the reservoir, expelling means or associated outlet means above a preset level, an amount of fluid in the reservoir below a preset level, a flow of current between the pair of electrodes outside a preset range, a low voltage condition for the voltage source, and a preset timer interval. However, Fischell discloses a fluid delivery device that includes generating an electrical stimulation alarm (Col. 8, lines 52-68; Col. 9, lines 1-8) to indicate the occurrence of various system conditions such as a fluid leak, lack of correlation between intended medication pumping and the pumping actually effected, low battery voltage, and low medication reserve (see Abstract, lines 3-10). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Fischell to modify the fluid delivery device with watchdog circuit of Say et al to include tests for these conditions. The motivation would have been to enable the device, which operates in a field where safety and reliability are paramount, to inform a patient of less than optimal system performance

(Fischell, Col. 3, lines 44-47). Therefore, it would have been obvious to combine Fischell with Say et al to obtain the invention specified in Claim 2.

- Regarding **Claim 3/2**, as related above, the combination of Fischell ant Say et al discloses the invention of Claim 2. Furthermore, Say et al further disclose that the control means is adapted to receive remotely generated commands and to control the fluid delivery device in accordance therewith, the predefined condition belonging to the group of conditions comprising: receiving a command from a predefined groups of commands, receiving a predefined command, and performing a predefined control action in response to a received command (Fig. 18B, element 99; Col. 37, lines 31-32; Col. 43, lines 30-34).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schulman (Patent No. 4345603) discloses a drug dispensing device with battery monitoring means and tingling sensation alarm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

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